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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,121	10/04/2000	Cynthia K. French	107-206-C	7802

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 02/26/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/680,121	FRENCH ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 November 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 39,40,42-45,48-50,56 and 57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 39-40, 42-45, 48-50, and 56-57 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Disposition of Claims

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

Response to Amendment

The Amendment filed November 20, 2002 (Paper No. 12) in response to the Office Action of May 20, 2002 is acknowledged and has been entered.

Claim 57 was added.

Claims 39-40, 42-45, 48-50, and 56-57 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Terminal Disclaimer

The terminal disclaimer filed on 11-20-02 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,218,523 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Rejections Maintained:

Claim 40 remains rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6,218,523 ('523). Applicants do not appear to have addressed this statutory rejection, but do attempt to explain certain inventorship corrections (Paper No. 12, page 5). However, changes in inventorship do not obviate a statutory double patenting rejection.

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Rejections in Part: (Claims 44 and 57 are now included in the rejections of record based on prior art)

Claims 43-45,49 and new claim 57 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier *et al.* (GeneBank Database, Accession No. AA081755, October 1996) for the reasons of record in Paper No. 10, page 4 and for the reasons set forth below.

Applicants argue (Paper No. 12, page 5) that each of claims 43, and 48-50 have been amended to require that the subject matter comprise at least 72 consecutive nucleotides of SEQ ID NO:1. This argument has been considered but is not found persuasive because 1) the nucleotides of Hillier *et al.* comprise at least 72 consecutive nucleotides of SEQ ID NO:1, and 2) amended claim 43 does not require "consecutive" nucleotides. Thus, the art still reads on a polynucleotide probe or primer of at least 72 nucleotides that specifically hybridizes to a nucleotide sequence selected from SEQ ID NO:1 or its complement. The art also reads on a polynucleotide probe comprising a polynucleotide encoding at least 72 consecutive amino acids, wherein the probe specifically hybridizes to a nucleotide sequence of SEQ ID NO:1 (Claim 57) because, inherently, the polynucleotide of Hillier would encode a peptide with at least 72 consecutive amino acids. Furthermore, the art reads on a probe or primer whose sequence is complementary to a nucleotide sequence from SEQ ID NO:1.

Likewise, claims 43-45, 49 and new claim 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsubara *et al.* (WO/9514772, sequence listing, June 1, 1995) for the

reasons set forth above. Matsubara *et al.* also teaches at least 72 consecutive nucleotides of SEQ ID NO:1.

Thus, applicant's arguments have not been found persuasive and the rejections are maintained.

New Objections/Rejections:

Claim 43 is objected to for a minor typographical error. The newly amended claim appears to have inserted a bracket (i.e., a “ [”) in front of the word “nucleotide” in line 1 of the claim.

Claim 50 is objected to for reciting “at least at least”. Appropriate corrections are required.

Claim 50 is further objected to for claiming a “polynucleotide” that comprises amino acids. The claim is objected to because although polynucleotides “encode” amino acids, the former does not comprise the same chemical composition as the latter. Appropriate corrections are required.

Claim 57 is objected to for a minor typographical error for reciting, “encoding of at least” in line 1 of the claim. Deletion of the word “of” would obviate this objection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 43, 50, 56, and 57, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39, 43, 48, 50, and 56-57 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of "72 nucleotides", "72 consecutive amino acids", or "100 consecutive amino acids" has no clear support in the specification and the claims as originally filed. This is a new matter rejection. Should applicant disagree with this rejection, applicant should submit evidence pointing to the serial number, page and line where support can be found for the disputed terminology.

Claims 39, 42, 48-50, and 56 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The written description in this case only sets forth an isolated Repro-PC-1.0 cDNA of SEQ ID NO:1 encoding a polypeptide comprising the amino acids of SEQ ID NO:2 and therefore the written description is not commensurate in scope with the claims drawn to naturally occurring polynucleotide sequences encoding various fragments of SEQ ID NO:2 (i.e., at least 72 or 100 consecutive amino acids) or non-specific immunogenic polypeptides of Repro-PC-1.0 (claim 42) which reads on allelic variants.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

The specification defines allelic variants (page 12) as any of two or more polymorphic forms of a gene occupying the same genetic locus and or cDNA’s derived from mRNA transcripts of genetic allelic variants, as well as the proteins encoded by them. However, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:1 and the encoded product (SEQ ID NO:2), the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required.

See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Thus, the instant disclosure (page 17, line 29) of a single species of nucleic acid and encoded polypeptide does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera.

Furthermore, the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”.

Therefore only an isolated Repro-PC-1.0 cDNA of SEQ ID NO:1 encoding a polypeptide comprising the amino acids of SEQ ID NO:2 meets the written description provision of 35 USC 112, first paragraph.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
February 25, 2003

